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# Biotechnology Notes

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**Biotechnology Notes**, a compilation of agency activities, news events, and upcoming meetings, is prepared for members of the U.S. Department of Agriculture's (USDA) Committee on Biotechnology in Agriculture (CBA) by USDA's Office of Agricultural Biotechnology (OAB).

## INSIDE USDA

### APHIS AMENDS BIOTECH REGULATIONS

A final rule goes into effect April 30 amending USDA's biotechnology regulations. The Department's Animal and Plant Health Inspection Service (APHIS) added a notification and a petition process as options to the existing framework for the introduction (import, interstate movement, release into the environment) of certain genetically engineered plants.

According to John Payne, Acting Director of APHIS' Biotechnology, Biologics and Environmental Protection (BBEP) division, the changes reflect the need to "bring into harmony" strict regulatory controls with an "abundance of scientific data" gathered over the last six years from almost 400 field tests conducted in most states. He added, "These changes will provide the researcher with options for complying with regulations by establishing performance standards that can be easily understood and followed."

#### ***The Notification Process***

Under the notification process, six crops -- corn, cotton, potato, soybean, tobacco, and tomato -- may now be imported, moved interstate, or field tested without first applying for an APHIS permit as long as certain eligibility criteria and the performance standards have been met. APHIS will still require information about the regulated article, such as the donor organism for all genes from which introduced genetic material was derived, the method used to transform the recipient, the size of the field test, and the date and location of the release. Notifications must reach APHIS at least 10 days prior to interstate movement and 30 days before the crop may be field tested or imported into this country. Detailed annual followup reports are also required.

Other crops may also be eligible for introduction under notification, on a limited basis, after a thorough case-by-case review which considers, among other things, the specific plant-gene combination and prior introductions under a permit.

## ***The Petition Process***

The petition process allows anyone to submit in writing to the Director of BBEP a request that a regulated plant should no longer be regulated. The petition must include detailed scientific information such as differences in the genotype of the regulated plant and nonmodified recipient organism, the nature and origin of the vector and the inserted genetic material, details about indirect effects on other plants, a detailed description of the phenotype of the regulated plant, and any information that may be unfavorable to a petition. All petitions will be published in the *Federal Register* for a 60-day public comment period. APHIS has up to 180 days to rule on the petition.

The biotechnology amendments were published in the March 31 *Federal Register*, Volume 58, Number 60, pages 17044-17059. For more information, please call Sally Van Wert, Biotechnology Permit Unit, APHIS, at 301-436-7612.

## **FINAL REPORT OUT ON DUBLIN COMMUNICATIONS MEETING**

A final report on a joint conference of the United States -- Commission of the European Communities workshop on "Methods of Communicating Biotechnology with the Public" has been published. The conference, which took place in March 1992 in Dublin, Ireland, included invited participants from the United States and the European Community. The workshop was an activity of the U.S.-EC Task Force on Biotechnology Research, a policy-level forum aimed at increasing mutual understanding and exchanging information on the scientific aspects of biotechnology. Copies of the report may be obtained from USDA's Office of Agricultural Biotechnology (OAB) by calling 703-235-4419; Fax: 703-235-4429.

## **GYPSY MOTHS UNDER ATTACK**

Researchers at USDA's Forest Service will be field testing a genetically altered form of a naturally occurring virus that attacks gypsy moths. The virus is registered as a pesticide with the Environmental Protection Agency (EPA) and is produced in limited quantities by the Forest Service in cooperation with APHIS laboratories. It has been used successfully in controlling gypsy moth larval populations as an alternative to synthetic chemical pesticides. This experiment is a followup to a similar one that began in 1989.

Commercial interest in producing the virus in quantity is contingent on increasing its potency and reducing production costs. Scientists hope that genetic engineering will help them achieve both goals.

But before the technology is perfected, researchers need to find out how long the genetically altered virus stays in the environment and how fast and far it spreads. That is the reason for the field trial. A "marker" gene will monitor dispersal of the virus.

The field trial was designed by the Boyce Thompson Institute, the Northeastern Forest Experiment Station (USDA/Forest Service), and the University of Massachusetts. A permit was issued by the EPA, and the field test will take place the middle of May on an experimental plot (100 meters square) at Otis Air National Guard Base in Cape Cod, Mass. To learn more about the experiment, please call Alan Wood at 607-254-1200.

## **BUILDING A BETTER FOREST THROUGH BIOTECHNOLOGY**

Although more than 133 million tree seedlings are planted each year in Texas, sometimes as many as half die during the first year, mainly due to severe summer droughts. Diseases and insects also take their toll on Texas trees, with the loblolly and slash pine being the hardest hit. The total cost of losses is estimated at about \$50 million a year. To help curtail the demise of these seedlings, researchers at the Texas Agricultural Experiment Station in College Station, Texas have turned to biotechnology.

Working at the molecular level, they recently developed the technology that can move desirable genes into slash pines and then clone the new tree. Plantings of slash pines in Texas have decreased in the past 10 years because the trees are highly susceptible to rust disease. But the new technology eventually may enable researchers not only to insert rust resistance into slash pines but to select a variety of specific traits for other tree species as well.

Other work is being carried out by forest geneticist Johannes Van Buijtenen, in collaboration with Warren Nance of USDA's Forest Service, to create a genetic "map" of the slash pine, the first such map for this important commercial tree. Molecular biologist John Cairney is attempting another first, characterizing drought-responsive DNA in the loblolly pine. The team at Texas has also found that a "promoter", or element that controls a gene, taken from a carrot, could function accurately in pine cells. To learn more about these and other reforestation projects, call Ron Newton at 409-845-8279.

## **NEWS AROUND THE NATION (AND THE WORLD)**

### **MEETING TO FOCUS ON FOOD BIOTECHNOLOGY**

If you have more questions than answers about the new foods that will be produced using advanced technology, then Research Triangle Park, NC may be the place to be June 28 and 29. There, an international group of scientists, sociologists, food processors, government officials, and lay people will share views at a conference entitled "Symbol, Substance, and Science: The Societal Issues of Food Biotechnology." The meeting is sponsored by the North Carolina Biotechnology Center (NCBC) and USDA's OAB. The conference takes place at the Conference and Education Facility of the NCBC

and will be followed by a meeting of USDA's Agricultural Biotechnology Research Advisory Committee June 30-July 1. For more information, please call Jill Nystrom at 919-541-9366.

## **BROCHURE, REPRINTS NOW AVAILABLE**

A brochure giving all the details about an upcoming meeting sponsored by the Institute for Science in Society (ISIS) is now available from either USDA's OAB or from ISIS. Entitled "A New Paradigm for Food, the Farm, and the Public: The Impact of Biotechnology," the conference will cover food labelling issues, transgenics, regulation, commercialization, global food issues, public policy, and communications, along with briefings from the executive branch of government and Congress. To request a brochure, please send a fax either to OAB at 703-235-4429 or to ISIS at 202-331-7543. Reprints of articles about biotechnology that have appeared in *Agricultural Research*, a publication of USDA's Agricultural Research Service, are now available. To request a copy, please send a fax to 703-235-4429.

## **THE CHINA-EC BIOTECHNOLOGY CENTER**

Two years ago China and the European Commission (EC) formed the China-EC Biotechnology Center (CEBC) to improve information exchange on biotechnological research in China and the EC. That union has resulted in several joint research projects concerning rice genetics, protein engineering, and nitrogen fixation. The CEBC is now working on plans for joint workshops that will focus on transgenic plants and protein engineering.

The CEBC publishes a quarterly newsletter, in English, that includes articles on Chinese and European research, information about funding for joint projects, reports on fellowships for Chinese scientists in European institutes, and profiles of research centers in both regions. A Chinese version of the newsletter is in the planning stages.

To learn more about the Center and its activities, either write to the China-EC Biotechnology Center, B7 Zaojunmiao - Haidan District Desk, 10081 Beijing, or to the European Commission, DGXII ISC Unit China Desk, 200, rue de la Loi, B-1049, Brussels, Belgium.

## **GENETICALLY MODIFIED BEER AND TOMATOES SLATED FOR TASTE TRIALS IN THE UK**

Beers produced using genetically modified yeasts and a genetically modified tomato may be the first of a series of novel foods to be taste tested in the United Kingdom. To

ensure that human studies are conducted safely, the UK's Advisory Committee on Novel Foods and Processes has established guidelines. In general the committee believes there is no need for a protocol if there is no hazard to human health, if the trial has been cleared with an ethics committee, records are kept, and all legal requirements have been met.

The guidelines are intended for use by industry and require a risk assessment as well as signed consent from a fully informed volunteer. To learn more about them, please write to Ms. C. Brock, Department of Health, Room 609, Eileen House, 80-94 Newington Causeway, London, SE1 6EF, England.

## IN CASE YOU WEREN'T THERE

■ Scientific issues related to the safety of food from transgenic animals was the topic du jour at a meeting of USDA's ABRAC Working Group on Transgenic Animals, April 8, in Washington, DC. The Department's Food Safety and Inspection Service (FSIS) asked ABRAC for scientific advice to help it in formulating policy regarding transgenic livestock and poultry.

FSIS presented the working group with three ways to group transgenic animals: changes that relate specifically to the animal, somatic cell and other cell therapy, and bio-pharm animals. The agency also posed a series of questions related to food safety and the different animal groups. The chairman of the working group, James Lauderdale, will present the group's recommendations at the next meeting of the full ABRAC, June 30-July 1, in Research Triangle Park, NC.

FSIS has not yet approved any transgenic animals for slaughter. It plans to use the existing experimental animal provisions of the Federal Meat and Poultry Products Inspection Acts in providing appropriate regulatory oversight. For more details, please contact Maryln Cordle, OAB senior regulatory specialist, at 703-235-1510.

■ The Food and Drug Administration's (FDA) Veterinary Medicine Advisory Committee met March 31 to consider whether the increase in mastitis in cows treated with Monsanto's bovine somatotropin (BST) product (Sometribove) would increase antibiotic use and pose a risk to human health. Twenty-six persons provided testimony during the portion of the meeting set aside for a public hearing. Some believed FDA should not approve Sometribove as an aid in increasing milk production, while others said FDA has sufficient information to grant approval.

The Advisory Committee agreed with FDA's and Monsanto's conclusion that there is an increase in mastitis due to the use of Sometribove, but the increase is small when compared to other influences on mastitis incidence, such as herd to herd variations, season, parity (the number of times a cow has given birth), stage of lactation, and herd

management practices. The Committee concluded that the risk due to an increased incidence in mastitis is manageable and that use of Sometribove would not adversely affect human health. For more information about the meeting, please call Richard Geyer at FDA on 301-295-8761.

## NEW PUBLICATIONS

■ "A Strategic Overview of Italian Biotechnology." Includes material on education and training, research and development activities, regulatory, and policy issues. Copies available from Benezech-Simpson & Co., Hameau de Bobon, 07610 Vion, France. Telephone: 33-750-68-630; Fax: 33-750-68-633.

■ "Methods of Communicating Biotechnology with the Public." December 1992. This is the final report of a U.S.-EC workshop that took place last year in Dublin, Ireland. To request a free copy, send a fax to 703-235-4429.

■ Minutes of the full ABRAC meeting (August 26-27, 1992) and the Working Group on Risk Assessment and Environmental Safety (August 25, 1992). To request copies, send a fax to 703-235-4429.

## UPCOMING MEETINGS

**April 28:** "The Risk of Risk Analysis for Federal Policymakers." A presentation to be given by Gail Charnley, Project Director, Committee on Risk Assessment Methodology, National Academy of Sciences. Event to be held at the Department of Transportation, 400 7th St., S.W., Room 6244, Washington, DC, from 9 a.m. to 10:30 a.m.

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**May 2-6:** Pest Management: Biologically Based Technologies. Beltsville, MD. Sponsored by USDA's Agricultural Research Service. For more details, please call 301-504-6108; Fax: 301-504-6357.

**May 23-26:** International Vectors in Recombinant Vectors in Vaccine Development. Albany, NY. Co-sponsored by USDA/APHIS, the National Institutes of Health, and the Food and Drug Administration. For details call Kathleen Cavanagh at 518-474-7760; Fax: 518-474-3439.

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**June 5-9:** 1993 Congress on Cell and Tissue Culture. "Growth Control: From the Receptor to the Nucleus. San Diego, CA. Sponsored by the Tissue Culture Association Inc. For details call 410-992-0946; Fax: 410-992-0949.

**June 10-11:** "A New Paradigm for Food, the Farm, and the Public: The Impact of Food Biotechnology." Washington, DC. Conference sponsored by the Institute for Science in Society. For details call Michael Gildenberg at 202-331-0613.

**June 14-16:** "Risk Assessment for Environmental Releases of Biotechnology Products." Duluth, Minnesota. Sponsored by EPA, Environment Canada, and USDA. For details call James Harvey at 904-934-9237.

**June 16-17:** Northeast University/Industry Technology Transfer Conference, LaGuardia Airport Marriott, New York. For details call 615-366-0679; Fax: 615-366-0695.

**June 28-29:** "Symbol, Substance, and Science: The Societal Issues of Food Biotechnology." Research Triangle Park, NC. Sponsored by the North Carolina Biotechnology Center and USDA's OAB. Call Jill Nystrom at 919-541-9366 for more details.

**June 30-July 1:** Meeting of USDA's ABRAC. Research Triangle Park, NC. For details call Daniel Jones at 703-235-4419.

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**July 11-16:** Gordon Conference on Applied Environmental Microbiology. Colby-Sawyer College, NH. Registration forms are available from the Gordon Research Conferences, University of Rhode Island, Kingston, RI 02881-0801. For more details call Carl Cerniglia at 501-543-7341.

**July 25-30:** "Third International Symposium on the Molecular Biology of the Potato." Santa Cruz, CA. Sponsored by USDA, Monsanto Inc., Frito Lay Inc., J.R. Simplot Inc., and Rhone Poulenc. For more information, please write to William Belknap, USDA-ARS, 800 Buchanan St., Albany, CA 94710.

**July 28-30:** Penn State's Twelfth Summer Symposium in Molecular Biology, "The Structure/Function Relationships in Proteins and Enzymes." University Park, PA. For details call Patricia Phillips at 814-863-3650; Fax: 814-863-1357.

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**Aug 17-20:** Plant Biotechnology Methods. This workshop introduces the principles, techniques, and applications of plant biotechnology. Sponsored by Penn State University. University Park, PA. For more information call either 1-800-833-5533 or 814-863-3650.

# A PRIMER FOR TEACHING ETHICS

Cheryll Reitmeier, Associate Professor of Food Science at Iowa State University, developed the following lesson plan for teaching ethics in her 200-level food science and human nutrition class called "Home Economics and Agricultural Systems in Contemporary Societies." Her class consisted of about 60 students that were divided into small discussion groups. The plan is reprinted with permission by the editor of *The Ag Bioethics Forum*. For more information, write to Reitmeier at Iowa State University, 110 MacKay Hall, Ames, Iowa 50011.

## Assignment

### I. To be completed before class.

A. Read the two assigned papers, pro and con.

For example:

Charles Blatz, "It is morally permissible to manipulate the genome of domestic hogs," and

Steve Sapontzis, "We should not manipulate the genome of domestic hogs," both in Journal of Agricultural and Environmental Ethics 4 (1991).

B. Your instructor will assign you one of the sides. Write three supporting statements for it.

C. Consider how your side is related to the moral principles defined in class:

Autonomy: The right of persons to have their own views and make their own decisions as long as they do not interfere with the autonomy of others.

Nonmaleficence: The avoidance of harm or risk of harm to others.

Beneficence: The performance of acts to benefit others.

Justice: Equals should be treated

equally and fairly, without discrimination based on race, gender, religion, etc.

### II. To be completed in class.

A. **Discussion Group 1.** (3 students with the same assignment)

1) Discuss your assigned problem and position. Each person should read his or her three supporting statements. (5 min.)

2) Agree on the 3 best supporting statements for your position (14 min.)

3) Write the statements down. (5 min.)

### B. **Discussion Group 2.**

Three students with the pro position join three students with the con position. They read each others' statements, then spend 30 minutes in class discussing the issue. They follow carefully the "Discussion Rules" listed below.

### III. To be completed after class.

A. Write three new supporting statements for your assigned view.

B. Cite the article, and the moral principles you are using to support the view.

C. State your personal position on the issue.

## Discussion Rules

1) Encourage everyone to participate.

2) Listen to all the information.

3) Listen to everyone's ideas, even if you do not agree.

4) Be critical of ideas, not people.

5) Focus on making the best discussions, not on "winning."

6) Ask for clarification of ideas that are not clear.

7) Consider all the ideas and facts supporting both sides of an issue.

8) Try to understand both sides of the issue.

9) Be open to changing your mind in response to new evidence or new ideas.

10) Express support and acceptance of others' ideas and conclusions.

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**Biotechnology Notes** is prepared by Marti Asner, USDA/OAB Information Specialist. Comments or news items are always appreciated and may be sent to: USDA/OAB, Room 1001, Rosslyn Plaza East, 14th and Independence Ave., S.W., Washington, DC 20250-2200. Telephone: 703-235-4419; Fax: 703-235-4429.